

- 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.
- 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.
- 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.
- 101.78 Health claims: fruits and vegetables and cancer.
- 101.79 Health claims: folate and neural tube defects.

Subpart F—Specific Requirements for Descriptive Claims that are Neither Nutrient Content Claims nor Health Claims

- 101.95 “Fresh,” “freshly frozen,” “fresh frozen,” “frozen fresh.”

Subpart G—Exemptions From Food Labeling Requirements

- 101.100 Food; exemptions from labeling.
- 101.103 Petitions requesting exemptions from or special requirements for label declaration of ingredients.
- 101.105 Declaration of net quantity of contents when exempt.
- 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

APPENDIX A TO PART 101—MONIER-WILLIAMS PROCEDURE (WITH MODIFICATIONS) FOR SULFITES IN FOOD, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION (NOVEMBER 1985)

APPENDIX B TO PART 101—GRAPHIC ENHANCEMENTS USED BY THE FDA

AUTHORITY: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

SOURCE: 42 FR 14308, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 101.1 Principal display panel of package form food.

The term “principal display panel” as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term “area of the principal display panel” means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package of cheese, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: *Provided, however,* That where such container presents an obvious “principal display panel” such as the top of a triangular or circular package of cheese, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 101.2 Information panel of package form food.

(a) The term “information panel” as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small

to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§101.4, 101.5, 101.8, 101.9, 101.13, 101.17, subpart D of part 101, and part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§101.105(h) (1) and (2) and 101.15.

(1) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in §101.1 is less than 10 square inches.

(iii) The label information includes:

(a) Nutrition labeling in accordance with §101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in §101.6.

(iv) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the

provisions of this paragraph (c) except that the type size is not less than three sixty-fourths inch in height.

(2) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a single "obvious principal display panel" as this term is defined in §101.1 and has no other available surface area for an information panel or alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in §101.1 is less than 12 square inches and bears all labeling appearing on the package.

(iii) The label information includes:

(a) Nutrition labeling in accordance with §101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in §101.6.

(iv) The information required by paragraph (b) of this section appears on the single, obvious principal display panel in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(3) Packaged foods are exempt from the type size requirements of this paragraph: *Provided*, That:

(i) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(ii) The label information includes:

(a) Nutrition labeling in accordance with §101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in §101.6.

(iii) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(4)(i) Soft drinks packaged in bottles manufactured before October 31, 1975 shall be exempt from the requirements prescribed by this section to the extent that information which is blown, lithographed, or formed onto the surface of the bottle is exempt from the

size and placement requirements of this section.

(ii) Soft drinks packaged in bottles shall be exempt from the size and placement requirements prescribed by this section if all of the following conditions are met:

(a) If the soft drink is packaged in a bottle bearing a paper, plastic foam jacket, or foil label, or is packaged in a nonreusable bottle bearing a label lithographed onto the surface of the bottle or is packaged in metal cans, the product shall not be exempt from any requirement of this section other than the exemptions created by § 1.24(a)(5)(ii) and (v) of this chapter and the label shall bear all required information in the specified minimum type size, except the label will not be required to bear the information required by § 101.5 if this information appears on the bottle closure or on the lid of the can in a type size not less than one-sixteenth inch in height, or if embossed on the lid of the can in a type size not less than one-eighth inch in height.

(b) If the soft drink is packaged in a bottle which does not bear a paper, plastic foam jacket or foil label, or is packaged in a reusable bottle bearing a label lithographed onto the surface of the bottle:

(1) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained shall bear nutrition labeling if required by § 101.9; and any vending machine in which it is contained shall bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.

(2) All other information pursuant to this section shall appear on the top of the bottle closure prominently and conspicuously in letters and/or numbers no less than one thirty-second inch in height, except that if the information required by § 101.5 is placed on the side of the closure in accordance with § 1.24(a)(5)(ii) of this chapter, such information shall appear in letters and/or numbers no less than one-sixteenth inch in height.

(3) Upon the petition of any interested person demonstrating that the bottle closure is too small to accommodate this information, the Commis-

sioner may by regulation establish an alternative method of disseminating such information. Information appearing on the closure shall appear in the following priority:

(i) The warning required by § 100.130 of this chapter.

(ii) The statement of ingredients.

(iii) The name and address of the manufacturer, packer, or distributor.

(iv) The statement of identity.

(5) Individual serving-size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, are exempt from type-size requirements of this paragraph, provided:

(i) The package has a total area of 3 square inches or less available to bear labeling;

(ii) There is insufficient area on the package available to print all required information in a type size of $\frac{1}{16}$ inch in height;

(iii) The label information includes a full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6 of this chapter; and

(iv) The information required by paragraph (b) of this section appears on the label in accordance with the provisions of this paragraph, except that the type size is not less than $\frac{1}{32}$ inch in height.

(d)(1) Except as provided by § 101.9(j)(13) and (j)(17), all information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as provided by § 101.9(j)(17), any vignettes, designs, and other nonmandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(2) Any food, not otherwise exempted in this section, if packaged in a container consisting of a separate lid and body, and bearing nutrition labeling pursuant to §101.9, and if the lid qualifies for and is designed to serve as a principal display panel, shall be exempt from the placement requirements of this section in the following respects:

(i) The name and place of business information required by §101.5 shall not be required on the body of the container if this information appears on the lid in accordance with this section.

(ii) The nutrition information required by §101.9 shall not be required on the lid if this information appears on the container body in accordance with this section.

(iii) The statement of ingredients required by §101.4 shall not be required on the lid if this information appears on the container body in accordance with this section. Further, the statement of ingredients is not required on the container body if this information appears on the lid in accordance with this section.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by §§101.4, 101.5, 101.8, 101.9, 101.13, 101.17, subpart D of part 101, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to part 10 of this chapter.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 42 FR 45905, Sept. 13, 1977; 42 FR 47191, Sept. 20, 1977; 44 FR 16006, Mar. 16, 1979; 49 FR 13339, Apr. 4, 1984; 53 FR 16068, May 5, 1988; 58 FR 44030, Aug. 18, 1993; 60 FR 17205, Apr. 5, 1995]

§101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.